



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

November 27, 2018

Re: Animal Welfare Assurance
#A3340-01 (OLAW Case 1A)

Dr. Roberto A. Osegueda
Vice President for Research
University of Texas – El Paso
500 W. University Avenue
Administration Building, (b) (4)
El Paso, Texas 79968-0587

Dear Dr. Osegueda,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 29, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Texas at El Paso, following up on an initial report on October 10, 2018. According to the information provided, OLAW understands that twenty mice received an inadvertent overdose of a hematological agent (hemin) and exhibited signs of illness. The incident was due to a miscalculation of the dosage by a graduate student.

The corrective actions consisted of the Principal Investigator contacting the veterinarian and then euthanizing the mice. The student was removed from the animal project, all solutions will now be verified and logged by the PI before administration, and a standard operating procedure was developed outlining all procedures and preparation of the solution.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



*Institutional Animal
Care and Use Office*

October 29, 2018

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892 (use 20817 for delivery service)

Re: Assurance D16-00221 (A3340-01)

Dear Dr. Morse:

The University of Texas at El Paso (UTEP), in accordance with PHS Policy IV.F.3., provides this report concerning an animal welfare issue. The IACUC office communicated the incident to OLAW with a preliminary e-mail report and requested a case be opened on October 10, 2018 on behalf of the IO.

Report:

The Attending Veterinarian (AV) notified the IACUC office on Wednesday, October 10, 2018 of an animal incident. Two groups of ten mice received a prepared dosage of hemin substance which resulted in an overdose. The IACUC Office notified the IACUC Chair and Institutional Official (IO) regarding the incident. The IACUC Chair did not assign a sub-committee because the adverse event was immediately corrected. The IACUC Chair met with the principal investigator (PI) on October 19, 2018 to discuss the details of the incident and explore additional measures that the PI can take to prevent future incidences. Details of the incident, corrective and recommended measures are outlined below.

Details of Incident:

On early Tuesday morning, October 9, 2018, a graduate student was assigned to prepare a stock solution of hemin to be injected into two groups of ten mice. That evening, a total of twenty mice received the prepared dosage. The principal investigator verified the dosage calculation after the mice were injected and noticed the calculations were incorrect. The PI immediately notified the AV about the incident and the mice were monitored. After further assessment, it was noted that the mice were reacting to the incorrect dosage and did not look healthy. LARC and the PI collaboratively decided to euthanize the mice.

Immediate Corrective Measures:

- The graduate student was immediately removed from the animal project

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*Institutional Animal
Care and Use Office*

Recommended Corrective Measures:

- In the future, each prepared solution will be verified by the PI before administration to mice.
- Verified calculations will be logged and signed off by the PI
- An SOP will be created to outline the procedures and include the preparation of the stock solution

I concur with the measures outlined above as The University of Texas at El Paso is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact me at (b) (6) or via e-mail at osegueda@utep.edu.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Roberto A. Osegueda, PhD
Vice President for Research
Institutional Official
The University of Texas at El Paso

500 W. University Ave.
El Paso, Texas
79968
(915) 747-6355
FAX: (915) 747-6063

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, November 26, 2018 4:01 PM
To: Inst Animal Care & Use Committee; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Osegueda, Roberto A.; [REDACTED] (b) (6)
[REDACTED] (b) (6)
Subject: RE: Assurance D16-00221 [A3340-01]; Preliminary Incident Report

Thank you for submitting this final report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Inst Animal Care & Use Committee [mailto:iacuc@utep.edu]
Sent: Monday, November 26, 2018 3:30 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Osegueda, Roberto A. <osegueda@utep.edu>; [REDACTED] (b) (6)
[REDACTED] (b) (6)
[REDACTED] (b) (6)
Subject: RE: Assurance D16-00221 [A3340-01]; Preliminary Incident Report

Good afternoon Dr. Morse,

Attached is the final report for the incident initially reported to OLAW on October 10, 2018.

If you have any questions or concerns, please feel free to contact our IACUC office.

Sincerely,

[REDACTED] (b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, October 11, 2018 9:27 AM
To: Inst Animal Care & Use Committee; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Osegueda, Roberto A.; (b) (6)
Subject: RE: Assurance D16-00221 [A3340-01]; Preliminary Incident Report

Thank you for this preliminary report (b) (6) We will open a case file and await your full report as noted.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
 Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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From: Inst Animal Care & Use Committee [mailto:iacuc@utep.edu]
Sent: Wednesday, October 10, 2018 5:52 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Osegueda, Roberto A. <osegueda@utep.edu>; (b) (6)
Subject: Assurance D16-00221 [A3340-01]; Preliminary Incident Report

Good afternoon,

On behalf of the Institutional Official, this email is to inform you of an overdose incident regarding a miscalculated dosage of a hemin mixture administered to a group of mice.

Today I received a phone call of an event that occurred yesterday evening. Overall, two groups of mice received a prepared dosage of hemin substance which resulted in an overdose. The PI notified the AV/ QA manager and the mice were euthanized shortly after.

Temporary corrective measures have been implemented and we request a case to be open for the incident. A more detailed report will be sent with the corrective actions at a later time.

Please contact the IACUC office if you have any questions. Thank you for your time.

Sincerely,

(b) (6)

(b) (6)